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R. Mahoney

Dated 29 August 2003

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- 7 AUG 2002

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Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The
Patent
Office

07AUG02 E739252-1 002835

P01/7700 0.00-0218310.1

The Patent Office

Cardiff Road
Newport
South Wales
NP9 1RH

1. Your reference

SJB/P11752B

2.

0218310.1

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3. Full name, address and postcode of the or of each applicant (*underline all surnames*)DePuy International Limited
St Anthony's Road
Leeds
LS11 8DTPatents ADP number (*if you know it*)

If the applicant is a corporate body, give the country/state of its incorporation

England

6004733002

4. Title of the invention

AN INSTRUMENT FOR PREPARING A BONE
CEMENT MATERIAL5. Name of your agent (*if you have one*)"Address for service" in the United Kingdom
to which all correspondence should be sent
(including the postcode)URQUHART-DYKES & LORD
TOWER HOUSE, MERRION WAY
LEEDS
LS2 8PAPatents ADP number (*if you know it*)

1644004

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (*if you know it*) the or each application number

Country

Priority application number
(*if you know it*)Date of filing
(day / month / year)

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application

Date of filing
(day / month / year)8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (*Answer 'Yes' if:*)

- a) any applicant named in part 3 is not an inventor, or
 - b) there is an inventor who is not named as an applicant, or
 - c) any named applicant is a corporate body.
- See note (d)

YES

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Continuation sheets of this form

Description 4

Claim(s) 1

Abstract

Drawing(s) 1

10. If you are also filing any of the following, state how many against each item.

Priority documents

Translations of priority documents

Statement of inventorship and right to grant of a patent (Patents Form 7/77)

Request for preliminary examination and search (Patents Form 9/77)

Request for substantive examination (Patents Form 10/77)

Any other documents (please specify)

11.

I/We request the grant of a patent on the basis of this application.

Signature

Date

12. Name and daytime telephone number of person to contact in the United Kingdom

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DUPLICATE

-1-

AN INSTRUMENT FOR PREPARING A BONE CEMENT MATERIAL

This invention relates to an instrument for preparing and delivering a bone cement material for deployment in orthopaedic surgery.

It is common to use bone cement materials to fix orthopaedic implants such as components of orthopaedic joint prostheses. The materials are commonly based on methacrylic acid and its esters. The materials are prepared by mixing two reactive components together. Reaction of the components involves polymerisation of the acid.

The reliability of the bond between a bone cement and adjacent bone tissue requires that the cement be injected into a bone cavity under pressure. This can improve the keying of the cement into the surface of the bone. It can also reduce the tendency for blood to exude from the surface of the bone, which itself can otherwise lead to weakening of the bond between the cement and the bone tissue, and weakening of the cement itself.

The present invention provides an instrument for preparing a bone cement material for deployment in orthopaedic surgery, which comprises a chamber in which components of the material can be mixed, and a sensor for measuring the pressure within the chamber.

Accordingly, in one aspect, the invention provides an instrument for preparing a bone cement material for deployment in orthopaedic surgery, the material being formed from two reactive components which, when mixed, react to form a useable cement, the instrument comprising:

- a. a chamber in which the components of the material can be mixed,
- b. a mixing tool which extends into the chamber, and which can be manipulated from outside the chamber, to cause the components of the material to mix,
- c. an outlet from the chamber through which the mixed material can be discharged from the chamber after it has mixed,

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-2-

- d. a piston which can be moved through the chamber to displace mixed material from the chamber through the outlet,
- e. a sensor for measuring the pressure within the chamber.

The instrument of the invention has the advantage that it enables greater accuracy to be achieved in the application of pressure to cement which is injected into a bone cavity. This can help to optimise the bond between the cement and the surface of the bone. It can also help to minimise the tendency for blood to exude from the bone at the surface where it contacts the cement.

The instrument of the invention has the further advantage that mixing of the cement material and its subsequent deployment can be accomplished, with control over the pressure that is applied to the cement, while the material is retained within the chamber and without exposure to atmosphere. This reduces the risk of contamination of the material, and also reduces the risk of exposure to the possibly harmful components of the cement.

Mixing devices for bone cement, which include discharge outlets for the cement after it has been mixed, are known. These include devices in which the piston which is used to discharge cement from the device forms one end of the chamber in which the cement is mixed. In some such devices, the discharge outlet is used during mixing of the cement to move the tool, for example by means of a shaft which protrudes from the outlet.

The mixing tool can move within the chamber to ensure mixing of the cement components. Preferably, the tool is capable of rotating about an axis defined by a shaft thereof, and is also capable of moving inwardly and outwardly along the axis defined by the shaft. These movements can be made manually, or using a motor or other drive. The mixing tool can have vanes on it. The mixing tool and the pressure sensor have to be positioned so that neither of them is damaged when the mixing tool is moved to cause the bone cement components to mix.

-3-

It can be preferred for the pressure sensor to be movable between a retracted or withdrawn position in which it allows the mixing tool to be used to mix the components, and an operative position in which it extends further into the chamber, into bone cement material in the chamber which has been mixed and is being allowed to react. The pressure sensor can be separable from the chamber so that they are supplied as separate parts. The pressure sensor can then be inserted into the chamber wall after the mixing step has been completed. For example, the chamber wall can have an opening which is closed by a plug or a cap or other closure. The pressure sensor can be positioned in the opening after removal of the plug.

The pressure sensor should be positioned within the chamber so that it can provide an accurate indication of the pressure to which cement being discharged from the chamber is exposed. For example, the sensor can be positioned in the end wall of the chamber, towards which the piston moves to displace cement from the chamber, or it can be positioned in the nozzle through which cement is injected into a bone cavity.

The pressure sensor can comprise at least one pressure switch or pressure transducer. Pressure might also be indicated by means of a component which changes configuration or shape or location when the pressure that is sensed by the sensor exceeds a pre-set limit. For example, it might comprise a pop-out plug which remains in place in a socket until the pressure that is sensed by the sensor reaches the pre-set limit, and then reverts to a popped configuration. The socket can have a bleed hole in its base which communicates with the interior of the chamber. The plug will be sealed into the socket, for example by a flexible polymeric seal which allows the plug to flex between its configuration prior to use, and its popped configuration.

Preferably, the instrument includes a data processor which is connected to the pressure sensor so that data from the pressure sensor can be transmitted to the data processor for analysis, to generate information concerning the pressure of material within the chamber. The information can be transmitted to the data processor wirelessly, for example, using radio or infrared communication. Generally, however, it will be preferred for the information to be transmitted using conductors.

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-4-

Use of a data processor has the advantage that it can provide a record of the measurements taken from the cement material in the chamber, which can be retained for later reference, for example with other records relating to the procedure. A data processor can be used to generate output information, for example for use by the surgeon. This information can be visual information, especially in graphical form. The information could be audible.

Embodiments of the present invention will now be described by way of example with reference to the accompanying drawings, in which:

Figure 1 is a diagrammatical side view illustration of the embodiment.

In the drawing the components are:-

1. Cement injection gun
2. Combined cement mixing chamber and delivery cartridge
3. Cement delivery nozzle
4. Pressure measuring sensor
5. Data processing unit
6. Visual, graphical, or audible display
7. Signal and power transmission cable.

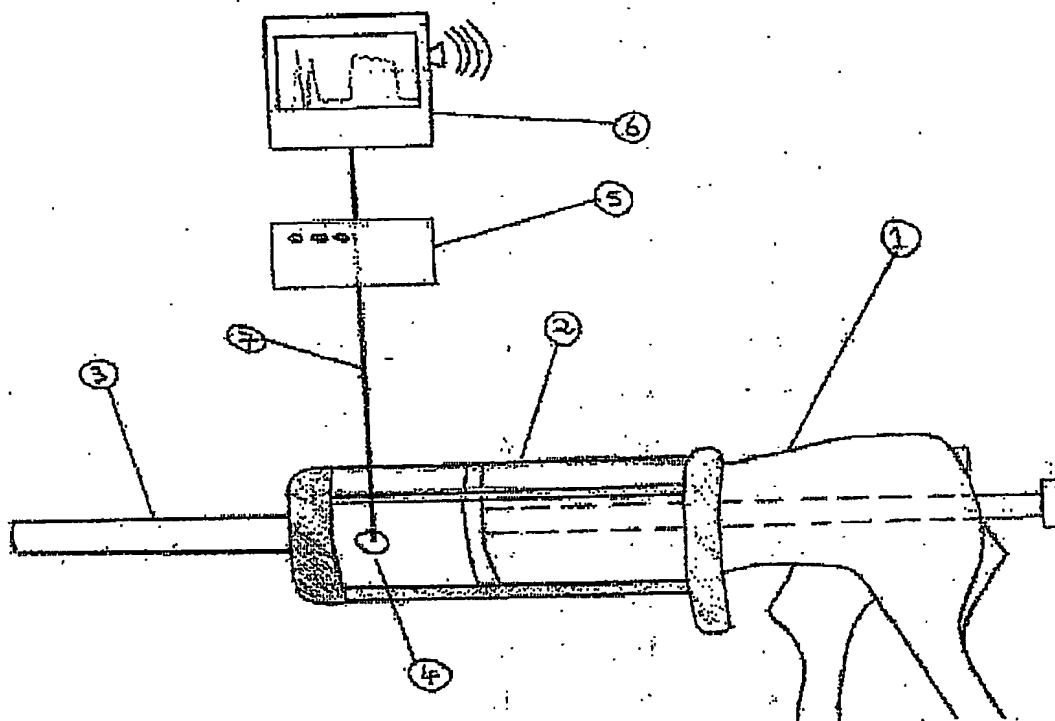
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CLAIMS:

1. An instrument for preparing a bone cement material for deployment in orthopaedic surgery, the material being formed from two reactive components which, when mixed, react to form a useable cement, the instrument comprising:
 - a. a chamber in which the components of the material can be mixed,
 - b. a mixing tool which extends into the chamber, and which can be manipulated from outside the chamber, to cause the components of the material to mix,
 - c. an outlet from the chamber through which the mixed material can be discharged from the chamber after it has mixed,
 - d. a piston which can be moved through the chamber to displace mixed material from the chamber through the outlet,
 - e. a sensor for measuring the pressure within the chamber.
2. An instrument as claimed in claim 1, in which the pressure sensor is located in the wall of the chamber towards which the piston moves to discharge mixed cement material through the chamber outlet.

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